September 20, 1996

Instruction Sheet
Owner’s Certification of Lasers as PMA Approved Devices

Attached is a sample form for your certification that the laser you own is identical in all relevant aspects to a PMA approved medical device. This sample form contains information adequate for such a certification. Also attached is a blank form which you may use for your certification.

Please submit the completed certification form to FDA for a determination of the adequacy of the certification. FDA will notify you in writing either that the information is determined to be adequate or inadequate. If the information is inadequate, an investigational device exemption (IDE) application is required.

The adequacy of the certification does not depend on any proprietary information. All of the information is available in the approval letter, the operator's manual, the Summary of Safety and Effectiveness Data, and the laser owner's (or agent's) experience with the laser.

Please send your completed certification, signed and dated, to:

Division of Physical Sciences
HFZ-130
Office of Science and Technology
Center for Devices and Radiological Health
12721 Twinbrook Parkway
Rockville, MD 20852

SAMPLE

Owner's Certification of Lasers as PMA Approved Devices

[The information adequate for certification is in parentheses.]

1. Name of manufacturer: Summit Technology ___ VISX ___

2. Model name and number: **[The model name and number of your Summit or VISX laser must be one with an approved PMA.]**

3. Serial number(s): **[Submission of this number is to ensure that the owner identifies a unique laser. This number is needed in case there are device failures, recalls or other actions required.]**

4. Ablation zone size(s): **[≤6.5 mm]**

5. Maximum energy per pulse: **[180mJ/cm², Summit; 160mJ/cm², VISX]**

6. Calibration techniques and schedule: **[The applicant states that the calibration techniques and schedule are the same as described in the appropriate operator's manual for the Summit or VISX laser.]**

7. Is the computer hardware, firmware, and software of your device identical to that distributed in the PMA approved device? **[Yes. This device is enabled only for those indications and conditions for which the model received PMA approval. Please obtain certification from a qualified engineering company and submit their certification as an attachment to your certification. This certification specifically excludes any computer hardware, firmware or software used to obtain fees for use of the device, e.g., Pillar Point counters.]**

8. Do you have a copy of the approved labeling, e.g., the appropriate operator's manual, a patient information brochure if provided, and other relevant material? **[Yes. This information is available through a Freedom of Information Act request.]**

I hereby make this Owner's Certification of Lasers as PMA Approved Devices to FDA with full knowledge that the making or submission of false statements represent violations of United States Code title 18, Chapter 47, Section 1001. Penalties include up to $10,000 in fines and up to five years imprisonment.

Signature of Owner (Certifier) Date_____

_____

Typed Name of Owner (Certifier) Address of Owner (Certifier)

_____ _____

Owner’s Certification of Lasers as PMA Approved Devices

1. Name of manufacturer: Summit Technology ___ VISX ___

2. Model name and number:

3. Serial number(s):

4. Ablation zone size(s):

5. Maximum energy per pulse:

6. Calibration techniques and schedule:

7. Is the computer hardware, firmware, and software of your device identical to that distributed in the PMA approved device?

8. Do you have a copy of the approved labeling, e.g., the appropriate operator's manual, a patient information brochure if provided, and other relevant material?

I hereby make this Owner’s Certification of Lasers as PMA Approved Devices to FDA with full knowledge that the making or submission of false statements represent violations of United States Code title 18, Chapter 47, Section 1001. Penalties include up to $10,000 in fines and up to five years imprisonment.

Signature of Owner (Certifier)

_____ Date_____

Typed Name of Owner (Certifier)

_____

Address of Owner (Certifier)